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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/441,242	11/16/1999	GIANDOMENICO RUSSO	8666-008-999	4066
20583	7590	07/27/2004		
JONES DAY 222 EAST 41ST ST NEW YORK, NY 10017			EXAMINER LEFFERS JR, GERALD G	
			ART UNIT 1636	PAPER NUMBER 12
DATE MAILED: 07/27/2004				

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/441,242

Applicant(s)

RUSSO ET AL.

Examiner

Gerald G Leffers Jr., PhD

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 16 July 2001.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 5-7, 13 and 17-19 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 6 is/are allowed.
- 6) ☒ Claim(s) 5, 7, 13 and 17-19 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 10/19/2000 *Paper #6*
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

Receipt is acknowledged of an amendment, filed 7/16/2001, in which nonelected claims were cancelled (claims 11-12, 14-16, 22-63, 65) and in which claims were amended (claims 5-6, 13 & 17). Claims 5-7, 13 and 17-19 are pending in the instant application.

Any rejection of record not addressed herein is withdrawn. This action is not final as there are new grounds of rejection made herein that were not necessitated by applicants' amendment of the claims in the response filed 7/16/2001.

### ***Sequence Compliance***

Receipt is acknowledged of a replacement paper copy of the sequence listing, computer readable form (CRF) and appropriate attorney's statements. The application is now in sequence compliance.

### ***Information Disclosure Statement (IDS)***

Receipt is acknowledged of an IDS filed 10/19/2000 that cites references of record in the prosecution of the parent application, 08/330,272. The signed and initialed PTO Form 1449 has been mailed along with this action.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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Claims 5, 13 and 17 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **This is a new rejection.**

Each of the claims comprises a limitation that the nucleic acid of the invention hybridizes under stringent conditions to a nucleic acid that consists of the complement of the nucleotide sequence of SEQ ID NO: 1 from nucleotide 49-387. There is no literal support anywhere in the originally filed specification or claims for the new limitation. Therefore, the amended claims comprise impermissible NEW MATTER.

Claims 18-19 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for isolated proteins comprising an amino acid sequence of at least 25 contiguous amino acids of SEQ ID NO: 2, does not reasonably provide enablement for embodiments where the protein does not comprise at least 25 contiguous amino acid residues of SEQ ID NO: 2. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. **This is a new rejection.**

Enablement is considered in view of the Wands factors (MPEP 2164.01(A)). These include: nature of the invention, breadth of the claims, guidance of the specification, the existence of working examples, state of the art, predictability of the art and the amount of

experimentation necessary. All of the Wands factors have been considered with regard to the instant claims, with the most relevant factors discussed below.

The rejected claims are drawn to isolated proteins having as little as 70% identity for as little as 25 or 50 amino acids of SEQ ID NO: 2. This encompasses a broad genus of proteins that have little or no correlation to the structural/functional characteristics of the protein described by SEQ ID NO: 2 (i.e. human TCL-1). The instant specification does not assign any particular biochemical functionality to the protein described by SEQ ID NO: 2 and there is no basis for the skilled artisan to envision the structural/functional characteristics of the protein described by SEQ ID NO: 2. The instant specification teaches that the ORF expressed to encode SEQ ID NO: 2 is involved in certain chromosomal rearrangements and that TCL-1 protein is associated with certain pathologies. Antibodies raised against the TCL-1 protein described by SEQ ID NO: 2 might therefore be useful in diagnostic methods for T cell pathologies associated with the expression of SEQ ID NO: 2. There is no teaching in the instant specification for how one would make and use a protein having only 70% identity, for example, over a segment of SEQ ID NO: 2 of only 25 or 50 contiguous amino acids. For example, there is no teaching as to how one would go about constructing such a polypeptide and then use the polypeptide to generate antisera that would necessarily recognize the human TCL-1 protein. Given that the protein described by SEQ ID NO: 2 was novel in the art at the time of filing, and given that the instant specification provides no significant guidance on how to use proteins having as little as 70% identity to SEQ ID NO: 2 over only 25 or 50 contiguous amino acid residues, the instant specification is not considered as enabling for the full, broad scope of the invention as currently recited in the rejected claims.

Claim 7 remains rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

**This rejection is maintained for reasons of record in the office action mailed as Paper No. 7 on 1/16/2001.**

***Response to Arguments/112 1<sup>st</sup> Rejection of Claim 7***

Applicant's arguments filed in the response of 7/16/2001 have been fully considered but they are not persuasive. The response essentially argues: 1) a patent does not have to describe exactly the subject matter claimed, 2) the skilled artisan would readily recognize the claimed genus of TCL-1 protein fragments based on the structural characteristics of the protein described by SEQ ID NO: 2 and the functional characteristics disclosed in the specification for specific binding of anti-TCL-1 antibodies, 3) the skilled artisan can readily make and determine whether a TCL-1 fragment falls within the metes and bounds of claim 7, 4) the skilled artisan can make and use the claimed fragments of TCL-1 protein without undue experimentation.

Arguments directed to the ability of the skilled artisan to experimentally determine which fragments of the protein described by SEQ ID NO: 2 can be bound by an anti-TCL-1 antibody are better suited to an enablement rejection. The instant claim is rejected for lack of a written description of the broad genus of fragments of the protein recited in claim 6 that will necessarily bind an anti-TCL-1 antibody. Neither the instant specification or applicants' arguments presented in the response provide a basis for the skilled artisan to envision those embodiments

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that will necessarily meet the functional limitations of the claims. For example, it is noted that the claim is directed to a protein fragment that can be specifically bound by an antibody to "a TCL-1 protein" without specifying which TCL-1 protein obtained from which source was used to obtain the antibodies used to bind the fragment. For reasons of record there is simply no way based upon the instant specification and the prior art for the skilled artisan to envision other embodiments of the TCL-1 protein obtained from other species. How then can the skilled artisan envision those fragments of the TCL-1 protein described by SEQ ID NO: 2 that bind an antibody against a protein the skilled artisan cannot even envision? Therefore, the skilled artisan would not have been able to envision a sufficient number of specific embodiments to describe the broadly claimed genus of protein fragments. The skilled artisan would reasonably have concluded applicants were not in possession of the claimed genus of polypeptide fragments of SEQ ID NO: 2 that bind an anti-TCL-1 antibody.

### *Conclusion*

This action is not final. Claims 5-7, 13, 17-19 are pending, with all but claim 6 rejected. Claim 6 is allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gerald G Leffers Jr., PhD whose telephone number is (571) 272-0772. The examiner can normally be reached on 9:30am-6:00pm.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Gerald G Leffers Jr., PhD  
Primary Examiner  
Art Unit 1636

ggl

  
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